K130649

510(k) Summary

NOV 0 1 2013

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name and Address of Applicant

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B. Contact Person

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C. Date Prepared

October 23, 2013

D. Device Name

Trade Name:	Silk Road™ Access Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter

E. Device Classification

Classification:	21 CFR§870.1250
Product Code:	DQY, KRA
Device Class:	Class II

F. Predicate Device

Silk Road Medical, Inc. submits that the subject Silk Road™ Access Catheter is substantially equivalent to the predicate, Penumbra Neuron™ Intracranial Access System (K070970, K082290).

G. Device Description

The Silk Road Access Catheter is a sterile, non-pyrogenic, single-use access catheter indicated for introduction of interventional devices into the peripheral vasculature. The Silk Road Access Catheter is a single-lumen, coil-reinforced shaft, variable stiffness catheter in a range of diameters and working lengths to accommodate target anatomy. All sizes contain a radiopaque marker on the distal end and a catheter hub on the proximal end. The catheter shaft has a hydrophilic coating on its distal portion to reduce friction during use. The catheter is offered with a dilator in all but the smallest size (SR-045-AC). The Silk Road Access Catheter is a limited duration (<24 hours), external-communicating devices, contacting circulating blood.

H. Indications for Use

The Silk Road Access Catheter is indicated for the introduction of interventional devices into the peripheral vasculature.

I. Technological Comparison

The Silk Road Access Catheter has similar features as compared to the predicate device as shown in the table below:

Manufacturer Model Name 510(k) Number	Penumbra Neuron™ Intracranial Access System K070970, K082290	Silk Road Medical Inc. Silk Road Access Catheter K130649
Indications for Use	The Neuron™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Silk Road™ Access Catheter is indicated for the introduction of interventional devices into the peripheral vasculature.
Anatomical Locations	Peripheral, Coronary, and Neuro Vasculature	Peripheral Vasculature
Materials-Catheter shaft	PTFE Lined, nylon co-polymer catheter, with hydrophilic coating	Same
Materials-Catheter Shaft Support	Stainless Steel	Same
Catheter Shaft Construction	Proximal – braid reinforced Distal – coil reinforced	Full length coil reinforced
Radiopacity	Radiopaque marker at distal tip	Same
Sterilization Method	EO	Same
Tip Configuration	Straight	Same

Manufacturer Model Name 510(k) Number	Penumbra Neuron™ Intracranial Access System K070970, K082290	Silk Road Medical Inc. Silk Road Access Catheter K130649
Catheter Dimensions	Neuron 6F Delivery Catheter Inner Diameter: 0.053"– 0.070" (1.3–1.8 mm) Outer Diameter: 0.067"–0.079" (1.7–2.0 mm) Working Length: 95–115 cm (37.4" – 45.3")	Access Catheter Inner Diameter 0.045"–0.078" (1.1–2.0 mm) Outer Diameter 0.057" 0.090" (1.4–2.3mm) Working Length 47–64 cm (18.5" – 25.2")
Delivery Aid Component and Dimensions	Component: Neuron 5F Select Catheter Inner Diameter 0.040" (1.0 mm) Outer Diameter 0.065" (1.6 mm) Working Length 120-130 cm (47.2 – 51.2")	Component: Dilator Inner Diameter 0.021"–0.042" (0.5–1.1 mm) Outer Diameter 0.052"– 0.072" (1.3–1.8 mm) Working Length 63 – 80 cm (24.8" – 31.5")
Supplied Accessory Devices	Rotating Hemostasis Valve (RHV) Peel away guidewire introducer (Note: The Neuron Delivery Catheter and the Neuron Select Catheter are both part of the Neuron Intracranial Access System but are supplied separately)	Dilator (dimensions noted above)

The technological characteristics and principals of operation of the Silk Road Access Catheter is substantially equivalent to the named predicate device.

J. Non-Clinical Performance Data

The following table contains the non-clinical testing which was conducted to support a determination of substantial equivalence to the predicate device.

Attribute	Acceptance Criteria	Result
Visual Inspection and Dimensional Verification	All samples must pass visual and dimensional inspection specifications.	Pass
Simulated Prep and Use	All samples must be able to be prepped and used per the IFU.	Pass
Coating Particulate	All samples must track through the track fixture and meet USP 788 microscopy method.	Pass
Coating Integrity	All samples must easily track through the track fixture	Pass
Guidewire-Microcatheter Advance/Withdrawal Force	All samples must pass advancement and withdrawal force	Pass
Bonding Stiffness	Characterize Bend Stiffness	All samples are acceptable
Aspiration Rate	Characterize Aspiration Rate	All samples are acceptable
Flush Rate	Characterization Flush Rate	All samples are acceptable
Tensile Test	All bonds must withstand a set force dictated by the device outer diameter for all samples	Pass
Shaft Kink Resistance	The distal and proximal shaft must not kink around the bend for all samples.	Pass
Torsion Test	All samples shall show no evidence of damage (kinking, flattening, separation) to any joints or bonds	Pass
Liquid Leakage	All samples shall show no water leaks large enough to form a falling drop over the entire device	Pass
Air Leakage	All samples shall show no bubbles are present	Pass
Luer Functional Testing	All samples shall meet the requirements of ISO 594-2 (gauging, separation force,	Pass

Attribute		Acceptance Criteria	Result
		unscrewing torque, ease of assembly, resistance to overriding and stress cracking).	
Biocompatibility	**Cytotoxicity: MEM Elution L-929 ISO/USP**	The test article passes if the mouse fibroblast cells do not display signs of toxicity after examination at 24, 48 and 72 hours.	**Result** - The test article scored '0' at 24, 48, and 72 ± 4 hours. **Conclusion** – The test article is considered non-cytotoxic under the conditions of this test.
	Sensitization: Maximum Sensitization (Guinea Pig)	The test article passes if the animals do not have signs of a delayed allergic response after being exposed to the test extract when compared to a control group.	**Result** - None of the negative control animals challenged with the control vehicle were observed with a sensitization response greater than '0'. None of the animals challenged with the test article extracts were observed with a sensitization response greater than '0'. The normal saline extract of the test material had a sensitization response of '0' under valid test conditions. The cottonseed oil extract of the test material had a sensitization response of '0' under valid test conditions. **Conclusion** - The test article did not elicit a sensitization response.
	Irritation: ISO Intracutaneous Reactivity Test	The test article passes if the difference between the mean scores for the test article extract and control are less than or equal to 1.0.	**Result** - The differences in the mean test and control scores of the extract dermal observations were less than 1.0. **Conclusion** - The ISO Intracutaneous Reactivity Test have been met by the test article.
	Systemic Toxicity: ISO Acute Systemic Injection	The test article passes if the animals exposed to the test article extract do not show signs of toxicity greater than the concurrent control groups over a 72 hour period.	**Result** - None of the test article extract treated animals were observed with clinical signs consistent with toxicity at any of the observation periods. Body weight changes were within acceptable parameters over the course of the study. **Conclusion** - These findings indicate that the requirements of the ISO Acute Systemic Injection Test have been met by the test article.
	Systemic Toxicity: Material Mediated Pyrogen	The test article passes if the animals exposed to the test article extract do not show significant increase in body temperature over a 3 hour period.	**Result** - The baseline temperatures for all the rabbits in this study were within 1 °C at the start of the test and no animals had a baseline temperature above 39.8 °C or less than 38.5 °C. During the 3 hour observation period, none of the rabbits administered with the test article extract had a temperature rise 0.5 °C at the required observation time points. **Conclusion** - The test article was determined to be non-pyrogenic.
	Hemocompatibility: Four Hour Thromboresistance Evaluation in Dogs	The test articles are considered thromboresistant if 1) the test animals survive general anesthesia and a study observation interval without test article complications; and 2) the blood test results, pre/post	**Result** - Implantation of the test and control devices in the jugular veins of two canines resulted in no adverse effects or clinical signs. There was minimal thrombus formation associated with one test device that was

Attribute		Acceptance Criteria	Result
		weight differences, and patency and thrombus scores are not subjectively different between the test and control articles	unremarkable given the absence of anticoagulants during the implant period. Additionally, the combined analysis of APTT, platelet counts, device weights, and clinical observations indicated that neither animal's clotting abilities were compromised after implantation of the devices. **Conclusion** - The test devices appear to have similar thromboresistance characteristics as the control devices.
	Hemocompatibility: Complement Activation C3a and SC5b-9	The test article passes if complement activation in human plasma (C3a Assay and SC5b-9) is not induced significantly when compared with the comparison article.	**Results** - The test article and the comparison article were evaluated for their capacity to activate the complement system. Under the conditions of the C3a assay, test article group one, group two, and the comparison article exhibited activation at 6017 ng/mL, 8239 ng/mL, and 6048 ng/mL. This was 3.0%, 8.3%, and 3.0%, respectively, of the normalized C3a concentration produced by CVF. Under the conditions of the SC5b-9 assay, test article group one, group two, and the comparison article exhibited activation at 4212 ng/mL, 13020 ng/mL, and 4047 ng/mL. This was 0.1 %, 2.3%, and 0.0%, respectively, of the normalized SC5b-9 concentration produced by CVF. **Conclusion** - All biomaterials have the potential to affect the make-up of the complement components of the blood. However, at this time there are no ranges or levels established as acceptable.
	Hemocompatibility: Platelet and Leukocyte Count	The test article passes if the counts are statistically and adversely significant compared to the reference material and comparison article.	**Result** - Test article group one results for the leukocyte and platelet counts showed 96% and 103%, respectively, of the reference material. Test article group two results for the leukocyte and platelet counts showed 100% and 105%, respectively, of the reference material. The comparison article results for the leukocyte and platelet counts showed 98% and 114%, respectively of the reference material. **Conclusion** - While all biomaterials have the potential to affect the make-up of the various components of the blood, at this time there are no ranges or levels that have been established as acceptable.
	Hemocompatibility: Partial Thromboplastin	The test article passes if the PTT is not significantly shortened following contact with a material under	**Result** - Both test article groups and the comparison article had an average clotting time of 300.0

Attribute		Acceptance Criteria	Result
	Time (PTT)	standardized conditions.	seconds. This value was found to be 100% of the negative control. **Conclusion** - Both test article groups and the comparison article are considered to be non-activators of the intrinsic coagulation pathway and pass the test.
	Hemocompatibility: Hemolysis – Direct Contact and Extract (ASTM F 756)	The test samples are rated per the hemolytic index above the negative control. If 0 – 2%, classified as non-hemolytic, if 2.1-5%, classified as slightly hemolytic, and if ≥5.1%, classified as hemolytic.	**Results** - **Direct:** The negative control replicates returned a hemolytic index of 0.1 %. The positive control replicates returned a hemolytic index of 11.8%. The test article returned a hemolytic index value equal to that found in the negative control and fell within the non-hemolytic range. **Extract:** The negative control replicates returned a hemolytic index of 0.1 %. The positive control replicates returned a hemolytic index of 14.7%. The test article returned a hemolytic index value lower than that found in the negative control and clearly fell within the non-hemolytic range. **Conclusion** - The test article is considered non-hemolytic under the test conditions employed and passes this test.
	Genotoxicity: Bactorial Mutagenicity Test-Ames Assay	The test article passes if the criteria for positive mutagen are not met	**Results** - The test article did not induce substantial increases in reversion rates of the type that are associated with mutagenesis. Furthermore, no substantial test article toxicity was noted that may have interfered with the ability of the test system to detect mutagens. As none of the tester strains showed an increase in reversion rates when treated with the test article, the test article is determined not to have caused an increase in point mutations, exchanges or deletions. **Conclusions** - The test article is considered non-mutagenic.
	Genotoxicity: *In Vitro* Mouse Lymphoma Assay	The test article passes if the mutant frequency is less than 1.8 fold higher than that of the concurrent negative control groups.	**Results** - The controls for the assay performed as required; qualifying both the assay and cell culture system as valid. The mutant frequencies and cloning efficiencies of preparations treated with test article were within the limits defined for a negative response. **Conclusion** – The test article is considered to be non-mutagenic (non-genotoxic and non-clastogenic) in this test system.
	Genotoxicity: *In Vivo* Mouse Micronucleus Assay	The test article passes if it does not show a significant increase in the number of micronucleated polychromatic erythrocytes.	**Result** - In general there were no apparent gross manifestations of toxicity nor biologically significant erythropoietic disturbances resulting in delayed mutagenesis.

Attribute	Acceptance Criteria	Result
		Furthermore, there were no biologically significant increases in mPCE production in the test article treated groups as compared to the concurrent negative controls. **Conclusion** - The test article is considered non-mutagenic in this test system.
Packaging Validation	Packaging must maintain product sterility and protect the product during shipment and storage.	**Pass**
Sterilization Validation	Silk Road Access Catheter must be validated ISO 11135-1:2007	**Pass**
Shelf Life	Silk Road Access Catheter must perform to specification and the package must maintain a sterile barrier during the shelf-life period as labeled on the product label.	**Pass**

Safety and Performance Testing - Animal
A GLP animal study was performed to evaluate the safety, performance and handling of the Silk Road Access Catheter as compared to a control device. Based on pathology and histopathology results, the safety acceptance criteria for the study were met. Performance and handling observations were made based on detailed characteristics of the device. No untoward observations were found by the clinician.

The physical, mechanical and *in vitro* and *in vivo* performance testing of the subject Silk Road Access Catheter demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate.

K. Conclusions

The Silk Road Access Catheter has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Silk Road Access Catheter functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 1, 2013

Silk Road Medical, Inc.
% Mr. Richard M. Ruedy
Vice President, RA/CA/QA
735 North Pastoria Avenue
Sunnyvale, CA 94085

Re: K130649
Trade/Device Name: Silk Road™ Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: September 20, 2013
Received: September 23, 2013

Dear Mr. Ruedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -A

Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130649

Device Name: Silk Road™ Access Catheter

Indications For Use:

The Silk Road™ Access Catheter is indicated for the introduction of interventional devices into the peripheral vasculature.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Victor Krauthamer -A
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